



Patient Information Sheet

Venlafaxine hydrochloride (marketed as Effexor)

This is a summary of the most important information about Effexor. For details, talk to your healthcare professional.

FDA ALERT [07/2005] – Suicidal Thoughts or Actions in Children and Adults

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

Children

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Although Effexor is prescribed for children, FDA has not approved Effexor for use in children.

Adults

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Effexor?

Effexor is in a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs).

Effexor is used to treat depression.

Effexor XR is used to treat:

- Depression
- Generalized anxiety disorder (GAD)
- Social anxiety disorder (SAD)

Who Should Not Take Effexor?

Never take Effexor if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor

(MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Effexor close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.
- **Stopping Effexor:** Do not stop taking Effexor suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **High blood pressure and heart problems:** You may get high blood pressure or a faster heart.
- **Bleeding problems:** Effexor may cause bleeding problems.
- **Mania:** You may become unusually hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking Effexor close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking Effexor late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Weight loss:** Effexor can cause weight loss.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, sleepiness, dry mouth, dizziness, difficulty sleeping and constipation.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver, kidney, or heart disease, or glaucoma. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Effexor may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take.
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Effexor?

- Effexor is taken by mouth, with food, exactly as prescribed by your healthcare professional.
- Swallow Effexor XR capsules whole. Do not crush or chew them. You may open the capsule, sprinkle the





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contents on a spoonful of applesauce, and take right away without chewing. Then follow with a glass of water.

Is There Anything Else I Need To Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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*Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
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